

## PDB102

## RETROSPECTIVE ANALYSIS OF THE ECONOMIC BURDEN AMONG CUSHING'S DISEASE PATIENTS IN THE U.S. MEDICAID PROGRAM

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**OBJECTIVES:** To evaluate the economic burden among patients diagnosed with Cushing's disease (CD) in the U.S. Medicaid program. **METHODS:** Patients diagnosed with CD (International Classification of Disease, 9<sup>th</sup> Revision, Clinical Modification (ICD-9-CM) diagnosis code 255.0) were identified using U.S. Medicaid data from 01 January 2008 through 31 December 2010. The initial diagnosis date was designated as the index date. A matching comparator cohort was created including patients of the same age, race and gender but without a CD diagnosis, and a randomly-chosen index date to minimize selection bias. Patients in both cohorts were required to be age  $\geq 18$  years, with continuous medical and pharmacy benefits for 1 year pre- and 1 year post-index date. One-to-one propensity score matching (PSM) was used to compare health care costs and utilizations during the follow-up period between the diseased and comparison cohorts, and was adjusted for baseline demographic and clinical characteristics. **RESULTS:** After risk adjustment by PSM, a total of 340 patients in each cohort were matched. CD patients had significantly higher health care utilization, including inpatient admissions (36.18% vs. 12.53%,  $p < 0.0001$ ) and long-term care (5.29% vs. 2.06%,  $p < 0.05$ ), other service (100% vs. 94.12%,  $p < 0.0001$ ) and pharmacy visits (84.41% vs. 78.24%,  $p < 0.05$ ), compared to those without the disease. CD patients incurred significantly higher inpatient (\$4,688 vs. \$1,139,  $p < 0.05$ ) and pharmacy costs (\$4,054 vs. \$2,100,  $p < 0.001$ ) compared to those without CD. Long-term care and other service costs incurred were higher for CD patients, compared to comparison patients, but were not statistically significant. **CONCLUSIONS:** In the current study, CD patients in the U.S. Medicaid program had a higher burden of illness in terms of health care resource utilization and costs, compared to those without a CD diagnosis.

## PDB103

## THE POTENTIAL VALUE OF ONGOING SUPPORT IN TYPE-1 DIABETES MELLITUS WITH DAFNEPLUS: EXPLORATORY PRE-TRIAL COST-EFFECTIVENESS ANALYSIS ON PROPOSED TRIAL END-POINT TARGET FOR 12-MONTH HBA1C IMPROVEMENT

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**OBJECTIVES:** The Dose Adjustment For Normal Eating (DAFNE) structured education programme is shown to be effective both in terms of clinical outcomes and cost-effectiveness outcomes in the treatment of T1DM. DAFNEplus aims to revise the DAFNE 5-day curriculum based on psychological and sociological findings in DAFNE, input from DAFNE graduates and emerging knowledge around behavioural science and technological developments. The current suggested primary endpoint is for the DAFNEplus programme to have an additional 20% DAFNE participants (70% in total) achieve either, (a) a reduction of at least 0.5% in HbA1c, or (b) to have an HbA1c below 7.5% (58.5 mmol/mol), at 12 months. This paper undertakes pre-trial what-if cost-effectiveness analyses concerning the DAFNEplus programme, which aim to be useful both in the design of the intervention itself and of the proposed trial. **METHODS:** The Sheffield Type 1 Diabetes Policy Model is an individual patient-level simulation model of T1DM. It includes long-term microvascular (retinopathy, neuropathy and nephropathy) and macrovascular (myocardial infarction, stroke, revascularization and angina) diabetes-related complications and acute adverse events (severe hypoglycaemia and diabetic ketoacidosis). Econometric methods were used to obtain the target level of HbA1c responders in the DAFNEplus arm. **RESULTS:** DAFNEplus would be considered as cost-effective if the additional spending on the intervention would be limited to £455–£751 per patient per year, depending on the assumptions on the length of maintenance period for the HbA1c benefit and the target HbA1c responder endpoint (70% in total) being achieved in the future trial. To achieve a more favourable cost-effectiveness probability of 80%, for example, the additional per patient per year cost should be restricted to £393–£574 range. **CONCLUSIONS:** Pre-trial modelling has enabled a clear understanding of the threshold range for the annual cost of DAFNEplus, which is still being designed, in order to be considered as cost-effective at the £20,000/QALY threshold.

## PDB104

## THE COST-EFFECTIVENESS OF SAXAGLIPTIN WHEN ADDED TO METFORMIN AND SULPHONYLUREA IN THE TREATMENT OF TYPE 2 DIABETES MELLITUS IN SPAIN

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**OBJECTIVES:** In patients with type 2 diabetes mellitus (T2DM), when blood glucose is not adequately controlled by the combination of metformin (MET) and sulphonylurea (SU), the clinician has to choose between adding a third oral drug or starting insulin therapy. The objective of this study was to assess the cost-effectiveness in the Spanish setting of adding saxagliptin (SAXA) to MET and SU, compared to adding basal insulin (INS). Additionally, the SAXA strategy was compared with a thiazolidinedione (TZD), also added on top of MET and SU. **METHODS:** The published and validated CARDIFF long-term diabetes model was used to estimate the direct medical costs and quality-adjusted life years (QALYs) associated with each strategy. Clinical inputs were obtained from a network meta-analysis. Based on the United Kingdom Prospective Diabetes Study equations, the model predicted disease progression and occurrence of micro- and macro-vascular complications, including mortality. Costs and utilities were applied to complications, hypoglycaemias and body mass index changes. The perspective of the Spanish Healthcare System was adopted over a lifetime horizon, at a discount rate of 3% (costs and health outcomes). Univariate and probabilistic sensitivity analyses were conducted. **RESULTS:** SAXA add-on to MET plus SU resulted in a dominant strategy compared to INS add-on to MET plus SU, providing a gain of

0.377 QALYs (95% CI: -0.227 to 0.754) and cost savings of €264 (95% CI: -€1,879 to €2,768). At a willingness-to-pay threshold of €30,000 per QALY gained, SAXA strategy had an 82% probability to be cost-effective. Compared to TZD add-on to MET plus SU, the triple therapy with SAXA reached an incremental cost-effectiveness ratio of €2,610 per QALY gained. **CONCLUSIONS:** Saxagliptin was predicted to be a cost-effective option in Spain when a new drug needs to be added in T2DM patients inadequately controlled with metformin and sulphonylurea alone.

## PDB105

## THE COST-EFFECTIVENESS OF DAPAGLIFLOZIN IN COMBINATION WITH INSULIN FOR THE TREATMENT OF TYPE 2 DIABETES MELLITUS (T2DM) IN SPAIN

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**OBJECTIVES:** To assess the cost-effectiveness of dapagliflozin, a sodium-glucose co-transporter-2 (SGLT-2) inhibitor versus dipeptidyl peptidase-4 inhibitor (DPP4i) both added on top of insulin, or compared to insulin alone (±oral anti-diabetes agents) for patients who are inadequately controlled on insulin strategy. **METHODS:** The CARDIFF diabetes model was used. Clinical inputs were derived from a randomized clinical trial comparing dapagliflozin add-on to insulin with insulin alone, and network-meta-analysis for the comparison with DPP4i. Together with United Kingdom Prospective Diabetes Study (UKPDS) equations, the model predicts disease progression and the number of micro- and macro-vascular complications, along with diabetes-specific and all-cause mortality. The perspective of the Spanish health care payer was adopted over a lifetime horizon. Costs and utilities were assigned to the appropriate model parameters to calculate total Quality-Adjusted-Life-Years (QALYs) and total costs. Deterministic and probabilistic sensitivity analyses were conducted. **RESULTS:** Compared to insulin alone, dapagliflozin added to insulin was associated with 0.698 incremental QALYs (95%CI: 0.442; 1.211) at an additional cost of €1,508 (95%CI: €611; €1,517), resulting in an incremental cost-effectiveness ratio (ICER) point estimate of €2,159/QALY. Dapagliflozin was found to dominate DPP4i add-on to insulin, being associated with slightly less costs (-€51; 95%CI: -€913; €553) and higher QALYs (0.168; 95%CI: -0.007; 0.417). At a willingness-to-pay threshold of €20,000/QALY, the dapagliflozin strategy was estimated to have a 100% probability of being cost-effective when compared to the insulin alone, and a 98% probability when compared to the DPP4i strategy. These findings were shown to be robust to variation in range of model parameters. **CONCLUSIONS:** Dapagliflozin added on top of insulin was predicted to be a cost-effective (vs. insulin alone) and cost saving (vs DPP4i) alternative in Spain in combination with insulin for patients who are inadequately controlled with insulin treatment regimens.

## PDB106

## THE COST-EFFECTIVENESS OF TOLVAPTAN FOR THE TREATMENT OF HYPONATRAEMIA SECONDARY TO SYNDROME OF INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION IN SWEDEN

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**OBJECTIVES:** Tolvaptan is a selective vasopressin V2-receptor antagonist indicated for the treatment of adult patients with hyponatraemia (HN) secondary to syndrome of inappropriate antidiuretic hormone secretion (SIADH). To date there have been no published economic evaluations assessing the cost effectiveness of tolvaptan in this indication. The aim of this study was to evaluate the cost effectiveness of tolvaptan versus no active treatment (NAT) from a Swedish societal perspective. **METHODS:** The economic evaluation considers a hypothetical population of individuals with HN secondary to SIADH who have either failed to respond to fluid restriction or for whom the use of fluid restriction is not suitable. The analysis considers three clinically relevant patient populations within the SIADH indication: 'all SIADH', small-cell lung cancer (SCLC) and pneumonia. A discrete event simulation was developed to model the progression of individuals through multiple inpatient admissions over a 30 day time horizon (180 days in the SCLC scenario). Key sources of evidence included randomised controlled trials (SALT I & II) and observational data sources. Unit costs were collected from publicly available sources. Utility values were obtained from mapping the SF-12 scores from the SALT I & II trials to EQ-5D. The primary outcome of the analysis was the incremental cost-effectiveness ratio (ICER) expressed as a cost per quality-adjusted life-year (QALY). **RESULTS:** In the 'all SIADH' population tolvaptan was associated with reduced costs (SEK 5,778) and increased QALYs (0.0019) versus NAT and was therefore dominant. In the SCLC and pneumonia subgroups tolvaptan was also associated with reduced costs and QALY improvements. The results were most sensitive to the duration of tolvaptan treatment and the assumptions around duration of hospitalisation. **CONCLUSIONS:** In all populations considered (all SIADH, SCLC and pneumonia) tolvaptan was dominant compared to NAT being associated with reduced costs and increased QALYs.

## PDB107

## COST-EFFECTIVENESS OF EMPAGLIFLOZIN (JARDIANCE®) 10 MG AND 25 MG ADMINISTERED AS AN ADD-ON TO METFORMIN COMPARED TO OTHER SODIUM-GLUCOSE CO-TRANSPORTER 2 INHIBITORS (SGLT2IS) FOR PATIENTS WITH TYPE 2 DIABETES MELLITUS (T2DM) IN THE UK

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**OBJECTIVES:** To assess the cost-effectiveness of the novel SGLT2is empagliflozin 10mg and 25mg compared to other SGLT2is (canagliflozin 100mg, canagliflozin 300mg, and dapagliflozin 10mg) when administered as an add-on to metformin for the treatment of patients with T2DM in the UK. **METHODS:** A micro-simulation model was developed, based on the United Kingdom Prospective Diabetes Study (UKPDS68) and the Januvia Diabetes Economic (JADE) model, to estimate long-term diabetes-related complications, QALYs and costs in a cohort of T2DM patients initiating dual therapy. The model was populated with the results of a network meta-analysis that estimated

the comparative efficacy and safety across SGLT2is. Data gaps were completed with information derived from published sources, including previous cost-effectiveness analyses. The UK National Health Service (NHS) perspective was considered to estimate costs and QALYs over a patients' lifetime. **RESULTS:** There were small differences in efficacy and safety across SGLT2is, which resulted in minor QALY and cost differences across treatment combinations. On average, empagliflozin 25mg obtained incremental QALYs of 0.029 versus dapagliflozin 10mg and 0.019 versus canagliflozin 100mg, and incremental costs of £178 and £86, respectively, whereas both canagliflozin 300mg and empagliflozin 10mg were dominated by empagliflozin 25mg. This resulted in an incremental cost-effectiveness ratio (ICER) of £4,858 per QALY gained with empagliflozin 25mg vs. canagliflozin 100mg. However, the differences across treatments were not significant when 95% percentile confidence intervals were considered. These results were robust to a number of sensitivity analyses including a 10-year time horizon, BMI impact, discount rates and parameter values related to utilities, disutilities, adverse events, and discontinuation rates. **CONCLUSIONS:** Overall, differences in QALYs and costs were minor between SGLT2is used as add-on to metformin in UK T2DM patients. On average, empagliflozin 25mg was the most cost-effective strategy, with an ICER of £4,858 per QALY gained vs. canagliflozin 100mg.

#### PDB108

##### COST EFFECTIVENESS ANALYSIS OF FLASH GLUCOSE MONITORING FOR TYPE 2 DIABETES PATIENTS RECEIVING INSULIN TREATMENT IN THE UK

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**OBJECTIVES:** A small, minimally-invasive flash glucose monitor (FGM) has recently been developed. Arm sensors worn up to 14 days interact with a hand-held reader to convey 8 hours of continuous glucose level data. The reader stores data, communicating glucose control via trend charts. Economic evaluation of FGM vs. conventional blood glucose monitoring (BGM) has not been conducted. This analysis estimates potential cost-effectiveness of using FGM in UK insulin-treated type 2 diabetes mellitus (T2DM) patients. **METHODS:** The IMS Core Diabetes Model (CDM) was used for analyses, assuming a lifetime horizon (40 years). Patient characteristics were based on early FGM feasibility trial data. Effectiveness was measured in life years (LY) and quality-adjusted life years (QALY), with assumptions around FGM effectiveness based on expected benefits of use. These include: a) lower HbA1c by 0.35%-0.5% compared to BGM over the horizon; b) utility improvement due to fewer finger pricks of 0-0.03; c) minor hypoglycaemic event rate reduction of 0% or 50% compared to BGM due to potential improved glycaemic control. Cost data (direct costs only) were extracted from published literature and government sources, and inflated to 2013 GBP. Incremental cost-effectiveness ratios (ICERs) were estimated, and threshold analysis was performed to estimate potential total FGM sensor costs for each scenario. **RESULTS:** Based on assumptions above, the ICER for FGM vs. BGM ranges from £10,034-£29,068/QALY. With 0.5% HbA1c improvement, 0.01 utility benefit, and no difference in hypoglycaemic events, the ICER is £17,808/QALY. Assumptions around utility improvement have a larger ICER impact than HbA1c benefit or change in minor hypoglycaemic events. Threshold analysis shows that with a conventional ICER threshold (£30,000/QALY), £14,606-£27,956 can be spent on sensors over a lifetime across scenarios. **CONCLUSIONS:** Using an alternate glucose monitoring method could be cost-effective across a variety of clinical benefit and cost assumptions in T2DM (T1DM analysis forthcoming).

#### PDB109

##### COST EFFECTIVENESS EVALUATION OF CANAGLIFLOZIN IN COMBINATION WITH METFORMIN AND SULFONYLUREA IN COMPARISON TO NPH INSULIN IN THE TREATMENT OF TYPE 2 DIABETES MELLITUS IN POLAND

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**OBJECTIVES:** To evaluate the cost-effectiveness of canagliflozin, an active inhibitor of sodium glucose co-transporter – 2 (SGLT2), in triple therapy of diabetes as add-on to metformin and sulfonylurea compared to NPH insulin in combination with oral antidiabetics. Canagliflozin in clinical trial results showed effective glucose reduction, along with other benefits in diabetes treatment including weight loss and SBP reduction. Cost effectiveness analyses were conducted in the Polish setting from a public perspective in accordance with guidelines of Polish HTA Agency (PolAHTA). **METHODS:** The IMS CORE Diabetes Model was used to evaluate the cost-effectiveness of canagliflozin in triple therapy versus NPH insulin using Polish-specific data, where available. Clinical data were derived from mixed treatment comparison analysis of published studies, as there is no head to head trial comparing canagliflozin with NPH insulin. Direct costs were reported in Polish zloty and an annual discount rate of 5% and 3.5% were applied on costs and effects respectively. **RESULTS:** In a triple therapy as add-on to metformin and sulfonylurea canagliflozin is a cost-effective treatment option in comparison with NPH insulin with ICERs of 4 477 z<sup>3</sup> and 69 081 z<sup>3</sup> for canagliflozin 100 mg and 300 mg respectively. Associated QALY gains were 0,084 and 0,106. Both results are below defined in Polish reimbursement act cost-effectiveness threshold. **CONCLUSIONS:** These results suggest that adding Canagliflozin to dual therapy versus insulin intensification in patients inadequately controlled with MET+ SU would be a more efficient use of health care resources in the Polish setting.

#### PDB110

##### COST-EFFECTIVENESS OF EMPAGLIFLOZIN (JARDIANCE®) 10 MG AND 25 MG ADMINISTERED AS AN ADD-ON TO METFORMIN AND SULFONYLUREA (MET+SU) COMPARED TO OTHER SODIUM-GLUCOSE CO-TRANSPORTER 2 INHIBITORS (SGLT2IS) IN PATIENTS WITH TYPE 2 DIABETES MELLITUS (T2DM) IN THE UK

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**OBJECTIVES:** To assess the cost-effectiveness of the SGLT2is empagliflozin 10mg and 25mg compared to other SGLT2is (canagliflozin 100mg and canagliflozin 300mg) when administered as an add-on to MET+SU in patients with T2DM in the UK. **METHODS:** Long-term diabetes-related complications, QALYs, and costs were estimated for T2DM patients failing MET+SU. A micro-simulation model was developed based on the United Kingdom Prospective Diabetes Study (UKPDS68) and the Januvia Diabetes Economic (JADE) model. A network meta-analysis comparing efficacy and safety across SGLT2is was used to populate the model. Data gaps were completed with information derived from published sources, including previous cost-effectiveness models. Costs and QALYs were estimated over a patients' lifetime from the UK National Health Service perspective. **RESULTS:** Empagliflozin 10mg attained the highest QALYs (6.991, compared to 6.98 for canagliflozin 100mg, 6.978 for empagliflozin 25mg and 6.976 for canagliflozin 300mg) due to slightly better HbA1c, SBP and weight control, and a small number of non-severe hypoglycaemias, compared to higher doses. Canagliflozin 300mg was the most costly strategy (£32,087, vs. £31,217 for canagliflozin 100mg, £31,409 for empagliflozin 10mg and £31,557 for empagliflozin 25mg). Therefore, empagliflozin 10mg dominated both canagliflozin 300mg and empagliflozin 25mg, and resulted in an incremental cost-effectiveness ratio of £17,445 per QALY gained vs. canagliflozin 100mg. However, incremental QALY and cost differences were not significant based on 95% percentile confidence intervals. These results remained robust when sensitivity analyses were conducted, including utilities, adverse events, discontinuation, modelling of weight, impact of BMI, duration of effect, time horizon and discount rates. **CONCLUSIONS:** Differences in QALYs and costs between SGLT2is as add-ons to MET+SU were minor. On average, empagliflozin 10mg resulted to be the most cost-effective option for T2DM patients failing MET+SU when commonly accepted thresholds in the UK were considered, with an incremental cost per QALY of £17,445 compared to canagliflozin 100mg.

#### PDB111

##### ABSENTEEISM AND PRESENTEEISM IN A POPULATION OF PATIENTS WITH DIABETIC FOOT ULCERS IN POLAND

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**OBJECTIVES:** Diabetic Foot Syndrome (DFS) is a serious and common complication of diabetes, often leading to limb amputation and disability. Disability and productivity loss in patients with DFS can generate significant indirect costs and potentially significant economic consequences. The purpose of the study is to estimate productivity loss and indirect costs associated with foot ulceration in patients with DFS. **METHODS:** We conducted a prospective survey in a population of DFS patients with foot ulceration. Loss of productivity was measured with a modified WPAI questionnaire. Indirect costs of both absenteeism and presenteeism were estimated using the human capital approach on the basis of the measure of gross value added per employee. **RESULTS:** Nearly one third of respondents (32%) declared that foot ulceration was the direct reason why they abandoned their professional activity. 40% and 34% of respondents, respectively, were forced to limit or change their professional activity at some point in the past because of the foot ulceration. More than 40% of respondents who changed or limited their professional activity because of the foot ulceration experienced reduction in earnings by 22.9% on average. Mean absenteeism was estimated at 32.63% of the nominal working time, while presenteeism was estimated at 23.48% of real working time. Total annual indirect costs associated with productivity loss amounted to EUR 170.8 million, including EUR 117.3 million of the costs of sickness absence and EUR 53.5 million of the costs of presenteeism. **CONCLUSIONS:** Foot ulceration in patients with DFS is a common cause why patients are forced to give up or change their professional activity, which usually leads to a reduction in earnings. Indirect costs associated with foot ulceration in DFS impose a significant burden on the Polish economy. There is no rationale that would clearly link productivity loss associated with ulceration in DFS and the ulceration severity.

#### PDB112

##### EXAMINING THE ROLE OF INSULIN PEN DEVICES IN ACUTE CARE SETTINGS: A REVIEW AND ANALYSIS OF HEALTH RESOURCE UTILIZATION

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**OBJECTIVES:** Insulin administration in the acute care setting is an integral component of inpatient diabetes management. The current method of administration in acute care settings is by vial and syringe. The aim of this study was to evaluate the impact of insulin pen implementation in the acute care setting on patient and health care worker safety, and health resource utilization (HRU). **METHODS:** A review of published literature was conducted to identify how insulin pen devices in the acute care setting may impact inpatient diabetes management. Additionally, nurse researchers from the McGill University Health Centre conducted a pilot study in a 52-bed unit to quantify this impact in a local context. Together, the results of the literature search and the pilot served as the inputs to an economic model, developed in Excel v14. Costs for the volume of insulin dispensed, injection supplies, needlestick injury management, and nursing labour were assessed. **RESULTS:** Previous published studies have revealed that insulin pen devices have the potential to improve inpatient management through better glycemic control, increased adherence and improved self-management education. The combined results from the literature and pilot indicate that moving from vial and non-safety syringe to a passive safety pen in acute care results in total estimated annual cost savings of \$43,339.66, and 191.42 hours of nursing time saved (site with 52 beds dedicated to patients with diabetes). Cost savings from the adoption of a passive safety insulin pen were predicted based on reductions in insulin volume and needlestick injuries. For an institution of similar size using safety syringes, the move to a